

K080871



Nucletron

NUCLETRON B.V.

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Department of Health and Human Services
 Centre of Device and Radiological Health
 Office of Device Evaluation
 Special 510(k) section

APR 29 2008

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

As required by section 807.92(c)

Submitter of 510(k):

Company name: Nucletron Corporation
 Registration number: 1121753
 Address: 8671 Robert Fulton Drive
 Columbia, MD 21046
 Phone: 410-312-4100
 Fax: 410-312-4197
 Correspondent: Lisa Dimmick
 Director Assurance & Regulatory Affairs

Modified Device Name:

Trade/Proprietary Name: Titanium Needle Sets
 Common / Usual name: JAQ, Remote controlled radionuclide applicator system
 Classification name: 90 (Radiology)
 Classification: 21CFR892.5700 Class II

Legally Marketed Device(s)

Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	Interstitial Needle Set	K953946

Description:

The Titanium Needle Set as described in this submission is designed as an accessory to the Nucletron remote afterloading equipment, mHDR and is intended for interstitial Brachytherapy procedures.

Interstitial needles can be used for treatment of carcinoma where no lumen or cavity is available. More and more brachytherapy treatments are carried out where CT and MR based

imaging is used for volume and target delineation. The Titanium Needles are fully CT/MR compatible and can be used in order to have minimal artefacts on the acquired images.

The Titanium Needle is inserted into the treatment area, using standard interstitial insertion techniques. CT markers are inserted into the Titanium Needles for visualisation. Radiographic images are obtained to determine the precise location within the body. This information is then used for Brachytherapy treatment planning purposes.

The Titanium Needle Set is used as an accessory to the Nucletron microSelectron remote afterloaders.

Intended use:

The modified device has the same intended use as the legally marketed predicate device cited:

Titanium needles are intended for interstitial Brachytherapy procedures involving Nucletron mHDR remote afterloading equipment.

Summary of technological considerations:

The Titanium Needle Set is substantially equivalent to the cleared predicate device, Interstitial Needle Set, 510(k)#: K953946.



Name: Dick van Waes
Title: Vice President
Nucletron B.V.
Veenendaal, The Netherlands

18-02-2008
Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lisa Dimmick
Director Regulatory Affairs
Nucletron Corporation
8671 Robert Fulton Drive
COLUMBIA MD 21046-2133

APR 29 2008

Re: K080871
Trade/Device Name: Titanium Needle Sets
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: March 31, 2008
Received: March 31, 2008

Dear Ms. Dimmick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

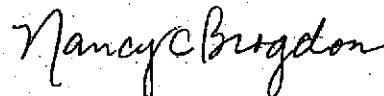
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k)
Number

K080871

Device Name


Titanium Needle Sets

Indications for
Use

Titanium needles are intended for interstitial Brachytherapy procedures involving Nucletron mHDR remote afterloading equipment.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K080871

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____